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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,486	07/22/2003	Bruno Amati	DX01551K	9131

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EXAMINER	
SANG, HONG	
ART UNIT	**PAPER NUMBER**
1643	

DATE MAILED: 03/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/625,486	AMATI ET AL.	
	Examiner	Art Unit	
	Hong Sang	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 July 2003*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-18* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

RE: Amati et al.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-9 and 13-18, drawn in part to a method of regulating cell proliferation comprising modulating the activity of a gene of Table 2, and a method of treating a subject suffering from a proliferative disorder comprising administering to the subject an effective amount of an agonist or antagonist of at least one gene of Table 2, classified in class 514, subclass 44, for example.

If applicants elect this group for prosecution on the merits, applicants are further required to select a single gene from Table 2, and a single binding composition or a single agonist or a single antagonist from claims 7, 8, 17 and 18 (i.e. an antibody, a soluble receptor, a nucleic acid, a small cell, a peptide mimetic of an antibody, a detectable label, and an anti-sense nucleic acid). This election should not be construed as an election of species. This is a restriction requirement. Each of the genes listed in Table 2 and each of the binding composition listed in claims 7, 8, 17 and 18 are structurally and functionally distinct molecules that would require separate search.

II. Claims 1, 3-9, 13 and 15-18, drawn in part to a method of regulating cell proliferation comprising modulating the activity of a polypeptide of table 2,

and a method of treating a subject suffering from a proliferative disorder comprising administering to the subject an effective amount of an agonist or antagonist of at least one polypeptide of Table 2, classified in class 424, subclass 130.1.

If applicants elect this group for prosecution on the merits, applicants are further required to select a single polypeptide from Table 2, and a single binding composition or a single agonist or a single antagonist from claims 7, 8, 17 and 18 (i.e. an antibody, a soluble receptor, a nucleic acid, a small cell, a peptide mimetic of an antibody, a detectable label, and an anti-sense nucleic acid). This election should not be construed as an election of species. This is a restriction requirement. Each of the polypeptides listed in Table 2 and each of the binding composition listed in claims 7, 8, 17 and 18 are structurally and functionally distinct molecules that would require separate search.

III. Claim 9-12, drawn in part to a method for the diagnosis of a proliferative condition comprising detecting or determining the expression of at least one gene of Table 2, classified in class 435, subclass 6.

If applicants elect this group for prosecution on the merits, applicants are further required to select a single gene from Table 2, and a single binding composition from claims 11 and 12 (i.e. an antibody, a soluble receptor, a nucleic acid, a small cell, a peptide mimetic of an antibody, a detectable label, and an anti-sense nucleic acid). This election

should not be construed as an election of species. This is a restriction requirement. Each of the genes listed in Table 2 and each of the binding composition listed in claims 11 and 12 are structurally and functionally distinct molecules that would require separate search.

IV. Claim 9-12, drawn in part to a method for the diagnosis of a proliferative condition comprising detecting or determining the activity of at least one gene of Table 2, classified in class 435, subclass 6.

If applicants elect this group for prosecution on the merits, applicants are further required to select a single gene from Table 2, and a single binding composition from claims 11 and 12 (i.e. an antibody, a soluble receptor, a nucleic acid, a small cell, a peptide mimetic of an antibody, a detectable label, and an anti-sense nucleic acid). This election should not be construed as an election of species. This is a restriction requirement. Each of the genes listed in Table 2 and each of the binding composition listed in claims 11 and 12 are structurally and functionally distinct molecules that would require separate search.

V. Claim 9, 11 and 12, drawn in part to a method for the diagnosis of a proliferative condition comprising detecting or determining the expression of at least one polypeptide of Table 2, classified in class 435, subclass 7.1.

If applicants elect this group for prosecution on the merits, applicants are further required to select a single polypeptide from Table 2,

and a single binding composition from claims 11 and 12 (i.e. an antibody, a soluble receptor, a nucleic acid, a small cell, a peptide mimetic of an antibody, a detectable label, and an anti-sense nucleic acid). . This election should not be construed as an election of species. This is a restriction requirement. Each of the polypeptides listed in Table 2 and each of the binding composition listed in claims 11 and 12 are structurally and functionally distinct molecules that would require separate search.

VI. Claim 9, 11 and 12, drawn in part to a method for the diagnosis of a proliferative condition comprising detecting or determining the activity of at least one polypeptide of Table 2, classified in class 435, subclass 4.

If applicants elect this group for prosecution on the merits, applicants are further required to select a single polypeptide from Table 2, and a single binding composition from claims 11 and 12 (i.e. an antibody, a soluble receptor, a nucleic acid, a small cell, a peptide mimetic of an antibody, a detectable label, and an anti-sense nucleic acid). This election should not be construed as an election of species. This is a restriction requirement. Each of the polypeptides listed in Table 2 and each of the binding composition listed in claims 11 and 12 are structurally and functionally distinct molecules that would require separate search.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions I-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of

operation, and effects (MPEP § 802.01 and § 806.06). The instant specification does not disclose that these methods would be used together. A method for regulating cell proliferation and treating a subject suffering from a proliferative disorder (groups I and II), and a method for diagnosing a proliferative condition (groups III-VI) are unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has a different mode of operation. Each invention performs this function using a structurally and functionally divergent material and comprises different methodological steps. For regulating cell proliferation and treating a subject suffering from a proliferation (groups I and II), a binding composition is administered to a cell or to a subject, for diagnosing a proliferative condition, the expression or activity of a gene or a polypeptide is determined by a detection assay. Therefore, groups I-II and groups III-VI are unrelated.

The inventions of groups I-II and groups III-VI further differ from each other in that each invention uses a structurally and functionally divergent material and comprises different methodological steps. For inventions of group 1, a gene is modulated, for group II, a polypeptide is modulated, for group III, the expression of a gene is determined, for group IV, the activity of a gene is determined, for group V, the expression of a polypeptide is determined, and for group VI, the activity of a polypeptide is determined. Because assays used for measuring the expression of a gene, the activity of a gene, the expression of a polypeptide, the activity of a polypeptide are different, therefore, groups I-VI are unrelated.

Furthermore, the distinct steps and products require separate and distinct searches. The searches for the inventions of groups I-VI are not coextensive. As such, it would be burdensome to search the inventions of Groups I-VI together.

3. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

4. Applicant is advised that the reply to this requirement to be complete must include (i) an election of invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hong Sang whose telephone number is (571) 272 8145. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hong Sang
Art Unit 1643
Feb. 17, 2006

LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER